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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,962	07/14/2000	Daniel C. Carter	P06652US0/BAS	6512

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/616,962	CARTER, DANIEL C.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-26,28 and 29 is/are allowed.
- 6) ☒ Claim(s) 27 and 30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Notice of Allowability, Prosecution Reopened

1. The above-identified application is being withdrawn from issue pursuant to 37 CFR 1.313.
2. The application is being withdrawn to permit reopening of prosecution.
3. U.S. Patent and Trademark Office records reveal that the issue fee and the publication fee have not been paid. If the issue fee and the publication fee have been submitted, the applicant may request a refund, or may request that the fee be credited to a deposit account. However, applicant may wait until the application is either again found allowable or held abandoned. If the application is allowed, upon receipt of a new Notice of Allowance and Issue and Publication Fee Due, applicant may request that the previously submitted issue fee and publication fee be applied toward payment of the issue fee and publication fee in the amount identified on the new Notice of Allowance and Issue and Publication Fee Due. If the application is abandoned, applicant may request either a refund or a credit to a specified Deposit Account.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al.
6. For convenience, Claim 27 is reproduced below:

27. (New) An isolated human serum albumin having an amino acid sequence that begins with His-Lys-Ser-Glu (SEQ ID NO: 2) at its N-terminal end.

7. Chan et al., page 525, left column, first two paragraphs under “Results” disclose N-terminal degradation of Human Serum Albumin (HSA). In particular, Chan et al., disclose, “N-terminal sequence analysis showed the presence of a secondary sequence, His-Lys-Ser-Glu- in addition to the major sequence Asp-Ala-His-Lys- representing the expected N-terminus (Fig. 2). This indicated that the smaller species seen on ES-MS represented HSA lacking the first two amino acids...” (Emphasis added) The prior art teachings of Chan et al., are deemed to anticipate the invention of claim 27.

8. Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al.

9. For convenience, Claim 30 is reproduced below:

30. (New) An isolated human serum albumin having an amino acid sequence that begins with Asp-Ala-X-Lys-Ser-Glu (SEQ ID NO: 4) at its N-terminal end wherein X represents an amino acid substitution, deletion or insertion which will provide sufficient steric hindrance so as to disrupt binding interactions sufficient to reduce or eliminate the binding of the albumin to metals.

As seen below in Figure 3 of Takahashi et al., an isolate or variant of HSA, named Nagasaki-3, has been found and is described as beginning at the N-terminus with the amino acid sequence Asp-Ala-X-Lys-Ser-Glu- where X is subject to single amino acid substitutions.

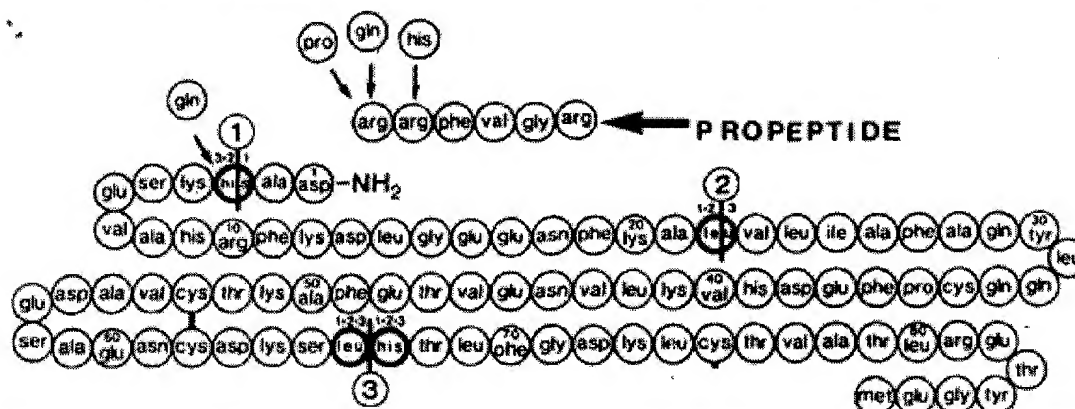


FIG. 3. Amino acid sequence of the propeptide and of the first CNBr fragment of normal serum albumin A. This figure is modified from Fig. 3 of Minghetti *et al.* (20), who determined the location of the introns 1, 2, and 3 (circled) and the codon positions at the introns. Single-amino acid substitutions in the propeptide for variant proalbumins and in the mature protein for albumin Nagasaki-3 are indicated by arrows pointing to the mutated site. Table 1 lists the variant proalbumins and gives the altered sequence of the propeptide.

Page 7407, left column further identifies the Nagasaki-3 variant as not a proalbumin and that it does have a substitution at His³.

Amino-Terminal Sequence Analysis and Radioautography of Other Albumin Variants. Amino-terminal sequence analysis was done for 30 or more cycles on a number of other albumin variants in the course of determining their structural changes. These included three Amerindian variants, albumins Naskapi, Yanomama-2, and Maku, and the Japanese variant Nagasaki-3. None of these proved to be proalbumins, and the first three mentioned have the normal amino-terminal sequence. However, Nagasaki-3 has the His³ → Gln substitution, which should affect the copper-binding site (N.T., Y.T., T. Isobe, F.W.P., M. Fujita, C. Satoh, and J. V. Neel, unpublished results). Radioautography with ⁶³Ni²⁺ indicated that the metal-binding affinity of Nagasaki-3 was decreased (Fig. 1). However, it was

10. While HSA is comprised of 585 amino acids and the amino acid sequence represented in Figure 3 is that of a CNBr fragment, the caption under the figure, and the text at page 7407, fairly identifies the Nagasaki-3 variant as one where the His position is both the third position in this variant and is also substituted. Such a teaching fairly anticipates the Human Serum Albumin

of claim 30 where the amino acid sequence begins with Asp-Ala-X-Lys-Ser-Glu (SEQ ID NO: 4) at its N-terminal.

Allowable Subject Matter

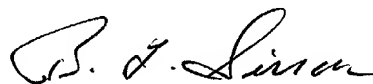
11. Claims 22-26, 28, and 29 are allowed.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 16, 2003